

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Etrivex shampoo may cause the following side effects

Common side effect (may affect up to 1 in 10 people):

- Skin burning sensation
- Inflammation of one or more hair follicles

Uncommon side effects (may affect up to 1 in 100 people):

- Endocrine disorders (such as adrenal suppression, Cushing syndrome), have been observed with potent topical steroids, especially when applied on large surface areas or used for prolonged periods
- Eye stinging or burning
- Eye irritation
- Ocular tight sensation
- Glaucoma
- Hypersensitivity
- Headache
- Pain of skin
- Skin discomfort
- Itching
- Acne
- Skin oedema
- Telangiectasia (veins under the surface of your skin may becoming more noticeable)
- Psoriasis aggravation
- Hair loss
- Dryness of the skin
- Urticaria
- Skin atrophy (thinning of your skin)
- Skin irritation
- Skin tightness
- Allergic contact dermatitis
- Erythema
- Rash

Not known (frequency cannot be estimated from the available data)

- Blurred vision

Irritation, itching, urticaria, visible small vessels or thinning skin around the treated areas are generally of a mild to moderate nature.

- If you have any signs of local intolerance, such as a burning sensation or redness to the areas that have been treated, do not use Etrivex shampoo until these symptoms have disappeared.
- Stop using the medicine and tell your doctor as soon as possible if you find your condition gets worse during treatment (this is more likely to happen if you have been using Etrivex shampoo longer than prescribed) or if you experience swelling of the eyelids, face or lips as you may be allergic to the product or have a skin infection.
- Using large amounts or keeping the product on the scalp for more than 15 minutes may:
 - cause the skin to become thinner so that it can damage more easily
 - allow the active substance to pass through the skin ; this can affect other parts of the body, especially in children, and during pregnancy
- Repeated courses of topical steroids over a long time may also sometimes cause, pustular eruptions (big pimples) and changes in hair growth and skin colour. Striae (stretch marks) and purpura (bruising) may become noticeable
- If you have rosacea (facial erythema associated with flushing of the skin, and possible papulopustules) the application of Etrivex shampoo on the face may cause your skin condition to worsen.
- Application of Etrivex shampoo on the face may induce perioral dermatitis (spotty red rash around the mouth).
- Application of Etrivex Shampoo to the skin may cause thinning of skin and therefore it should never be used on the face or on other areas of the skin than the scalp.
- In order to avoid interaction with hair colour dying product, such as hair colour changes, your shampoo should be thoroughly rinsed.
- If you have any unusual discomfort that you do not understand, tell your doctor as soon as possible.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

<https://yellowcard.mhra.gov.uk> or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance,
Website: www.hpra.ie

5. How to store Etrivex 500 micrograms/g Shampoo

Keep this medicine out of the sight and reach of children.

Do not use Etrivex Shampoo after the expiry date which is stated on the bottle and the carton. The expiry date refers to the last day of that month.

Store in the original plastic bottle in order to protect from light.

Discard the bottle 6 months after first opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

These measures will help to protect the environment.

6. Contents of the pack and other information

What Etrivex 500 micrograms/g shampoo contains

- The active substance is clobetasol propionate
- Each gram (millilitre) of Etrivex Shampoo contains 500 micrograms of the active ingredient Clobetasol propionate.
- The other ingredients are: ethanol, coco alkyl dimethyl betaine, sodium laureth sulfate, polyquaternium-10, sodium citrate, citric acid monohydrate and purified water.

What Etrivex 500 micrograms/g shampoo looks like and contents of the pack

Etrivex Shampoo is a thick, semi transparent liquid shampoo with an alcoholic smell that is colourless to pale yellow in appearance.

Etrivex shampoo is available on prescription from your doctor in white high density polyethylene (HDPE) plastic bottles of 60 ml or 125 ml fitted with polypropylene snap closure. The HDPE bottle of 30 ml is fitted with polypropylene screw closure. Bottles contain 30 ml, 60 ml or 125 ml of shampoo (not all pack sizes may be marketed).

Marketing Authorisation Holder and Manufacturer:

Marketing Authorisation Holder:

UK MAH:
Galderma (U.K.) Limited,
Evergreen House North,
Grafton Place,
London,
England,
NW1 2DX

IE MAH:
Galderma International,
Tour Europlaza,
20, Avenue André Prothin,
La Défense 4,
92927 Paris, La Défense, CEDEX,
France

PL 10590/0052
PA 22743/008/001

Manufacturer:

Laboratoires Galderma,
Z.I.- Montdésir
74540, Alby-sur-Chéran
France.

This medicinal product is authorised in the Member States under the following names:

United Kingdom (Northern Ireland), Italy, Ireland and Portugal: Etrivex 500 micrograms/g shampoo France, Germany, Belgium, Poland, Spain, Hungary, The Netherlands, Sweden, Denmark, Austria, Luxembourg, Iceland, Czech Republic, Norway, Greece, Slovakia and Finland: Clobex 500 micrograms/g shampoo

This leaflet was last revised in August 2022.